Testimony of Dr. Stuart Ginn
ENT – Head & Neck Surgeon, WakeMed Health & Hospitals
Medical Director, WakeMed Innovations
"FAA Reauthorization: Harnessing the Evolution of Flight to Deliver for the American People"
Before the Aviation Subcommittee of the House Committee on Transportation and Infrastructure
Thursday March 30, 2023 / 10:00 AM EDT

Chairman Graves, Ranking Member Cohen, distinguished Members of the Aviation Subcommittee, thank you for this opportunity to testify before you today to share my perspective on priorities associated with the upcoming FAA Reauthorization.

My name is Dr. Stuart Ginn, I am an ear, nose and throat (ENT) physician and surgeon at WakeMed Health and Hospitals in Raleigh, North Carolina, where I also serve as the hospital's Medical Director of Innovations. WakeMed is a private, not-for-profit healthcare system with three hospitals totaling 970 beds, including Wake County's only Level I Trauma Center, and several free-standing full-service Emergency Departments distributed across our community. WakeMed serves as the safety net hospital system serving one of the fastest-growing metropolitan areas in the United States and employs nearly 12,000 community members in our region. WakeMed is committed to improving the health and well-being of our community by providing outstanding and compassionate care to all and works to remain a leader in patient safety, innovation, and education.

Prior to working in healthcare for the past the past two decades, I began my career in aviation. At just 14 years old, I started learning to fly, earning my private pilot certificate and eventually becoming a certified flight instructor (CFI). Ultimately, I received my commercial pilot certification and subsequently served as a First Officer at a United Express carrier.

In my role as Medical Director of Innovations, I have had the privilege, over the past several years, to leverage both passions to bring advanced aviation technology to our health system in an effort to prove uncrewed aircraft systems (UAS) can be utilized to improve overall quality and access to healthcare. Our efforts, working with the North Carolina Department of Transportation (NCDOT) and all of our industry partners as part of the FAA's Integration Pilot Program (IPP) and BEYOND Programs, have been an incredible experience and we have learned a great deal.

I was so inspired by our efforts in North Carolina that I wanted to make sure that hospitals and health systems across the country were aware of these opportunities and had the basic tools necessary to get air operations up and running. So, in 2021, I co-founded the Coalition for Advanced Health Mobility (CAHM), where I currently serve as President.

What we've seen in advanced health mobility makes it clear that this technology can revolutionize healthcare access, save countless lives in emergency response situations, and bring health logistics to new levels of efficiency. However, we have also faced substantial barriers to implementation in our efforts to integrate and scale the technology to better serve our community. Over the next several minutes I would like to share my thoughts on how we can seize this opportunity and work collaboratively to find innovative solutions to break through the chokepoints keeping us from reaching full capability in this area.

Opportunity for UAS in Healthcare

UAS technology presents an incredible opportunity for both the aviation and healthcare industries. As an aviator, I can appreciate all the benefits that UAS bring, including lowering barriers to access, aviation-related jobs, and utilizing a greater percentage of the National Airspace System (NAS). As a healthcare professional, UAS present an opportunity to provide low cost, rapid response capabilities to deliver high-value medical payloads between facilities and directly to those in need, extending the reach of healthcare facilities and providers and delivering new forms of flexible healthcare infrastructure. The result is the ability to address critical public health needs using traditionally underutilized airspace while improving opportunities for access to aviation and achieving a high level of operational safety.

I've prepared three sample use cases which I believe represent relevant examples of how UAS are positioned to enhance public health.

Blood Product and Sample Delivery: A critical and feasible early use case is the creation of UAS routes connecting medical centers and enabling the expeditious transport of blood products to support trauma and critical care systems. Research has shown UAS can reduce blood product delivery times by 50%, improving outcomes for critically injured or ill patients.[1] Blood and laboratory samples, vaccines, testing kits, and other supplies can also be transported between facilities, greatly improving access to these supplies and devices and improving patient care. This is consistent with WakeMed's program findings when delivering blood samples across the WakeMed Raleigh Campus, reducing delivery times from 44 minutes per delivery on average to 20 minutes.

Emergency Response Delivery: Emergency medical services (EMS) continue to see rapid advancement in technologies, best practices, and potentially lifesaving tools that often take far too long to implement. UAS could become a front-line tool for emergency response systems. One of the most obvious examples is the delivery of automated external defibrillators (AEDs), which are compact, portable devices capable of delivering an electric shock to a patient in cardiac arrest. Patients who experience sudden cardiac arrest, who may have no prior medical history of heart disease, have a 5% survival rate in the United States.[2] According to the same study published by the American Heart Association, data shows survival rates from cardiac arrest double when bystanders apply an AED before emergency responders can arrive. Every minute that passes while a patient waits for defibrillation results in a 7% to 10% reduction in survival.[3] This presents a significant opportunity for UAS to be deployed for rapid delivery of AEDs to patients in the community where distance from a healthcare facility or personnel would otherwise impact their survival. There are many areas across the country where UAS delivery could dramatically reduce response times compared to traditional EMS due to terrain, population density, or traffic congestion. Other examples of emergency response applications include delivering epinephrine (EpiPen) for severe allergic reactions, Naloxone (Narcan) for treatment of overdoses, albuterol

[1] (Li, et al. 2022)
[2] (Pollack, et al. 2018)
[3] (Cheskes, et al. 2020)

rescue inhalers for respiratory distress, and glucose or dextrose for severe hypoglycemia, all potentially fatal conditions without immediate medical intervention.

Prescription and Medical Device Delivery: UAS may provide patients with the option to have their prescriptions or other healthcare devices to support virtual care services delivered via air transport. Access to reliable transportation to pick up prescriptions or receive in-person medical care may not always be an option, resulting in patients not receiving needed care. Remote health is also evolving rapidly in the wake of the pandemic, resulting in healthcare systems across the country prioritizing innovation in remote healthcare and expanding how health services are delivered. There are devices a patient can use at home that provide a virtual healthcare physician with important data needed for patient diagnosis and treatment. These devices could be delivered from a healthcare facility directly to a patient to support virtual care services.

While I focus this presentation on small UAS, there are ample use cases for crewed and uncrewed advanced air mobility (AAM) aircraft, as well. These would include emergency response, the transport of doctors and patients between facilities, and supporting larger medical cargo deliveries between centers and across larger regions. Please take this small subset of use cases as a glimpse of the potential for UAS to provide public health benefits, and note there are many use cases not discussed, such as organ transfer and natural disaster response, to name a few.

Progress in UAS Medical Package Delivery

The FAA's UAS Integration Pilot Program (IPP) was established in 2017 as the result of a presidential memorandum to enable enhanced drone integration into the NAS.[4] The program evaluated several use cases across diverse environments to collect data to inform regulatory changes necessary to facilitate safe, scalable, and repeatable operations, while also providing valuable data on the societal and economic implications of wide-scale implementation.

WakeMed joined the NCDOT IPP Lead Participant team because of the potential for UAS to support system growth, expand our geographic service footprint, address longstanding logistics challenges impeding care delivery, increase transparency in the supply chain, and work towards effective UAS integration into routine healthcare system operations. Other North Carolina healthcare systems delivered personal protective equipment (PPE), transfusion materials, pharmaceuticals, and vaccinations. NCDOT team partners completed about 12,000 medical package deliveries under the FAA IPP and have completed about 6,000 thus far under the FAA BEYOND Program.[5]

WakeMed's initial operation with UAS manufacturer Matternet and UAS operator UPS Flight Forward focused on the routine delivery of test samples from an outpatient surgical center and clinic to WakeMed's main campus laboratory. The UAS delivery augmented ground courier deliveries on the route and provided for faster, more efficient delivery of lab samples between those facilities. To enable this operation, UPS Flight Forward was required to obtain FAA approval to carry hazardous materials (HAZMAT) and local airspace coordination with medical helicopter operations

[4] (Trump 2017)
[5] (Block 2023)

was required. UPS Flight Forward went on to achieve the first Uncrewed Standard Part 135 Air Carrier certification from the FAA in 2019 and Matternet developed one of the first FAA type-certified UAS in the United States.[6]

Ultimately, WakeMed and our partners in the IPP completed 1,663 safe flights, serving 6,648 patients in need, and drastically cutting the average medical delivery time from an hour to only a few minutes, enabling patients to both rapidly receive a diagnosis and begin treatment.[7]

In August of 2021, WakeMed reassessed the cost-benefit of our UAS program to determine whether the program's demands and benefits aligned with the costs of competing priorities. The challenging decision was made to pause the UAS program on the basis that its limited scale did not support feasible economics or capabilities for the overall delivery system. This appears to be an emerging theme among other healthcare systems engaged in UAS innovation. While WakeMed remains a partner for the NCDOT BEYOND program, we, along with other healthcare systems, are unable to continue to financially invest in a technology that faces continued regulatory constraints towards commercialization and scalability.

Other healthcare systems across the country have also initiated pilot programs or demonstrations to investigate how UAS can improve healthcare services. In April 2019, the first organ was flown 2.8 miles from an organ procurement non-profit on the outskirts of Baltimore to the University of Maryland Medical Center in the city's urban core.[8] This delivery occurred outside of the IPP program but signaled to medical professionals and advocates in healthcare that we were on the precipice of substantial advancement in the industry. In January 2021, the State University of New York's (SUNY) Upstate University Hospital began UAS transport of COVID-19 testing kits from the downtown Syracuse hospital to nearby laboratories.[9] Other healthcare systems invested in UAS medical package delivery include University of California San Diego Health, Novant Health, Vidant Health, Atrium Health, Beaumont Health, Cardinal Health, Hutchinson Regional Health System, and others.

Challenges to UAS Medical Package Delivery

The largest impediment to healthcare systems deploying and sustaining UAS medical package delivery programs are the current regulatory constraints. Let me start by saying I think the FAA has worked under challenging circumstances to adapt regulations that have proven to be effective at maintaining U.S. leadership and safety in traditional crewed aviation. However, adapting and applying these regulations has been burdensome relative to the risk of the proposed operations. WakeMed would still be flying, potentially on a larger scale, if not for the immense regulatory constraints that ultimately made it too difficult to continue investment in the program.

For healthcare systems to adopt UAS technology, the operations need to be scalable with reasonable economics to support the financial investments in standing up and integrating a UAS

[6] (AUVSI News 2019); (Federal Aviation Administration 2022)
[7] (See Footnote 5)
[8] (Maryland Today Staff 2019)
[9] (Geddes 2021)

program. WakeMed learned this firsthand as program growth was significantly constrained by regulatory approval processes which were out of our control. Some examples of these pain points include: limitations on what types of payloads could be delivered with UAS, limited route expansion capabilities, restrictions on flying beyond visual line of sight (BVLOS), restrictions on flying over people and vehicles, and any significant level of automation. A healthcare system is highly incentivized by UAS operations that can quickly scale, adapt to new payloads as needs arise, and deliver across a larger geographic region in both rural and urban settings.

As an example, WakeMed attempted to implement a new use case at the beginning of the pandemic leveraging our existing UAS system to support an expanded COVID testing network. Our operator petitioned the FAA for operational approval with supporting documentation to deploy UAS for a distributed testing model to improve access to early COVID testing where it was desperately needed. The idea had broad support from within WakeMed and presented an opportunity to build on the successful deployment of UAS for lab specimen transport to uniquely support public health in our region. Ultimately, the request was not approved and the public health benefits we were trying to achieve could not be realized.

The constraints of scaling operations due to regulatory barriers have also limited healthcare investments in important infrastructure to sustain operations and improve operational efficiencies. These include investing in infrastructure integration, both physical and digital, developing multimodal transportation systems interfaces, integrating into the healthcare operation, and more. The pilot programs to-date have never truly relied on UAS to deliver medical packages; they have always been ancillary, with other transportation alternatives as the primary modes.

I am aware of several other healthcare systems who have also had to slow or pause UAS operations due to lack of regulatory progress to approve UAS operations. WakeMed is not an anomaly, this is happening across the United States as pilot programs struggle to transition into sustained operations. The technology is ready. The regulatory foundation is not.

What is Needed to Enable Public Health Benefits

The FAA has taken the approach of defining acceptable levels of risk for commercial and general aviation that considers air and ground risks in safety case analyses. The standards developed for crewed aviation have set a high bar for safety, which makes sense because an incident in the air is catastrophic to those directly impacted onboard and potentially non-participating individuals on the ground. The FAA has applied the same safety methodology and processes to UAS, targeting equivalent levels of safety for small uncrewed aircraft operating in the NAS. I believe the FAA's approach has been the most conservative, especially for existing airspace users to prevent mid-air collisions, but is a static approach for evaluating risk for UAS operations.

For operations that provide public health benefits, we should consider risk more holistically to include not only the risk to aircraft and people on the ground, but also the risk of not conducting an operation. This concept is referred to as dynamic risk where the risk of performing an operation is evaluated against the benefits that operation provides.

Dynamic risk has been well studied as a framework for adoption by several leading entities including NASA, the National Institutes of Health (NIH), and the American Institute of Aeronautics and Astronautics (AIAA). The FAA found in their IPP Final Report that identifying potential societal and economic impacts is important for safely integrating UAS package deliveries and recommended the FAA measure and quantify the societal and economic impacts of UAS operations. The FAA UAS Beyond Visual Line of Sight (BVLOS) Aviation Rulemaking Committee (ARC) Final Report recommended the FAA assess and evaluate the societal benefits and consider those benefits as part of the "overall risk and rewards balance". Additionally, MITRE, a Federally Funded R&D Center (FFRDC), released "A Holistic Approach for Assessing Drone Benefits, Safety, and Societal Acceptance" which outlines an approach for considering the potential risks and benefits of a proposed UAS operation as part of a broader NAS risk assessment.

Dynamic risk may be best understood through the AED delivery use case presented earlier. The risk of mortality after suffering from sudden cardiac arrest increases by 7% to 10% for every minute of delay before defibrillation.[10] A UAS could be launched, fly beyond visual line of sight, and drop an AED to nearby bystander to begin defibrillation all within minutes in a rural community, which may have otherwise taken up to 15 minutes for first responders to arrive. The previously mentioned study shows that UAS may arrive between 1.8 to 8 minutes faster compared to traditional medic units, resulting in a 12.6% to 80% improvement in the chance of survival. In this case, where every second matters, saving just a few minutes provides substantial public health benefits by improving the chance of an individual surviving following a cardiac arrest. Few would question the necessity of conducting this type of operation when the choice is between either increasing an individual's chance of survival by 80% versus the potential air and ground risk of flying a UAS the in the NAS at an altitude at or below 400 feet in a rural environment,

It is important to note the dynamic risk model does not suggest a reduction or decreased emphasis in aviation safety. No aircraft should fly beyond visual line of sight if it has not been designed to do so or if it does not have reasonable safety mitigations in place. What I am suggesting is to update the antiquated processes being adapted from traditional aviation to better align with the opportunities UAS may provide to benefit society and healthcare systems like WakeMed.

In addition, we need to understand the UAS industry is at an inflection point. Companies have been working tirelessly since before the FAA IPP kicked off in 2017, operating for years with little to no revenue or profit while awaiting development of a regulatory framework to enable UAS integration and scalability. Investment in use cases that support critical societal needs will enable further testing and data collection for advanced and complex UAS operations. The public has a higher tolerance for risk for use cases with clear public benefit. As such, public health applications should continue to be an early focal point for FAA programs especially for advanced UAS operations, such as BVLOS and highly automated operations. Safety data and best practices achieved in these high-value operations can then be utilized to enable further industry maturation.

[10] (See Footnote 3)

Summary and Recommendations

Healthcare systems have demonstrated a desire to integrate UAS into their day-to-day operations and to leverage the technology to deliver innovative services within their communities, creating substantial public health benefits. These benefits include increasing access to healthcare services, delivering lifesaving medicines and equipment within communities, and improving the economics of delivering healthcare, to name a few. Healthcare systems like WakeMed are ready to leverage the positive momentum from the IPP and BEYOND programs to develop scalable, flexible, UAS-based systems to augment healthcare infrastructure and enhance public health. Unfortunately, the current regulatory framework has inhibited innovation in the healthcare domain as lead times for regulatory approvals and operational economics have made it difficult to sustain investment in UAS programs. These challenges have also limited healthcare investment in internal infrastructure and integration that would enable broader adoption within the healthcare system.

I provide the Aviation Subcommittee two recommendations for consideration as part of the 2023 FAA Reauthorization:

1. **Include language in the FAA Reauthorization to recognize and utilize the concept of dynamic risk in approving operational requests that provide a clear public benefit.** Dynamic risk will leverage what has worked well for traditional aviation and right-size risk considerations against public benefit for public health and other operations that provide societal benefits.

2. **Include a funded pilot program in the FAA Reauthorization that will enable further testing, evaluation, and deployment of BVLOS and highly automated UAS operations in industries that provide clear public benefits.** The implementation of a dynamic risk model will require further testing and evaluation of UAS in real-world environments, in parallel to developing the necessary risk models.

Thank you for the opportunity to testify and I look forward to answering any specific questions from the Subcommittee.

Bibliography

AUVSI News. 2019. "UPS Flight Forward Awarded First Full Part 135 Standard Certification Operate UAS." *AUVSI Technology* 1. https://www.auvsi.org/industry-news/ups-flight-forward-awarded-first-full-part-135-standard-certification-operate-uas.

Block, Joseph, interview by Dr. Stuart Ginn. 2023. *Program Manager, North Carolina (DOT) Lead Participant - FAA BEYOND Program* (March).

Cheskes, Sheldon, Shelley L. McLeod, Michael Nolan, Paul Snobelen, Christian Vaillancourt, Steven C. Brooks, Katie N. Dainty, Timothy C. Y. Chan, and Ian R. Drennan. 2020. "Improving Access to Automated External Defibrillators in Rural and Remote Settings: A Drone Delivery Feasibility Study." *Journal of the American Heart Association.* https://www.ahajournals.org/doi/10.1161/JAHA.120.016687.

Federal Aviation Administration. 2022. "Airworthiness Criteria: Special Class Airworthiness Criteria for the Matternet, Inc. M2 Unmanned Aircraft." *Federal Register.* February 25. https://www.federalregister.gov/documents/2022/02/25/2022-03867/airworthiness-criteria-special-class-airworthiness-criteria-for-the-matternet-inc-m2-unmanned.

Geddes, Darry. 2021. "It's [a] bird. It's a plane. It's a Drone. ." *Upstate Medical University | News.* January 20. https://www.upstate.edu/news/articles/2021/2021-01-20-droneland.php.

Li, Qiang, Jing Xia, Fangmin Ge, and Mao Zhang. 2022. *Blood delivery by drone: a faltering step in a promising direction.* The Lancet Global Health, 1. https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(22)00272-8/fulltext.

Maryland Today Staff. 2019. "In a First, Unmanned Aerial System Delivers Organ for Transplant." *MarylandToday | Research.* https://today.umd.edu/first-unmanned-aerial-system-delivers-organ-transplant-53b72f5c-c800-4332-927c-b17b04e36601.

Pollack, Ross A., Siobhan P. Brown, Thomas Rea, Tom Aufderheude, David Barbic, Buick E. Jason, Jim Christenson, et al. 2018. "Cardiac arrest survival greatly increases when bystanders use an automated external defibrillator." *American Heart Association; Circulation Journal Report.* https://newsroom.heart.org/news/cardiac-arrest-survival-greatly-increases-when-bystanders-use-an-automated-external-defibrillator?preview=3165.

Trump, Donald J. 2017. "Presidential Memorandum for the Secretary of Transportation." *U.S. Department of Transportation .* October 31. https://www.transportation.gov/briefing-room/presidential-memorandum-secretary-transportation.